REMARKS

In order to distinctly claim the present invention, claim 1 has been replaced by a new claim 7 that specifies how assay throughput is increased by initially configuring the analyzer with reagent resources that are the only throughput limiting resources and then incrementally adding reagent resources to increase throughput as the number of assays within the original group of assays to be conducted increases. Applicant apologizes for any confusion that has arisen about new or different assays being conducted and single or multiple reagent addition assays being added.

Drawing Corrections

A replacement Figure 2 marked "Prior Art" accompanies this communication, as requested.

Claim Rejections –35 USC §112, first paragraph

In response to the Examiner's comments regarding the present rejection, it is important to recall the problem being addressed is that of a clinical laboratory faced with ever-increasing capital expenses to accommodate an increasing volume of incoming samples to be tested for an expanding menu of assays. In such a situation, the laboratory has two options: (1) install another analyzer to add capacity as demand increases or; (2) in accord with the present invention, add an extra module to a previously installed analyzer, wherein the previously installed analyzer had underutilized capacity because of the absence of that extra module. In the first instance, a greater "up front" expense will be incurred. The present invention offers the second option of initially installing an analyzer that is throughput-limited only because of the capacity of a single "processing module" and then adding "processing modules" as needed to increase analyzer capacity.

In the simplest example of a single reagent assay, wherein the analyzer is initially configured such that whichever operating resources are throughput limiting (for example, in Fig. 5, only one reagent server 26 enables a throughput of only 1000 assays per hour),

those resources may be incrementally added to the analyzer (as in Figs. 6 and 7) in order to increase throughput as incoming assay demand increases. Fig. 6 illustrates two reagent servers enabling a throughput of 2000 assays/hour and Fig. 7 illustrates the analyzer with three servers operating at its maximum throughput.

In order to explain the Examiner's issue with paragraph [0028] and the conclusion that the "application does not teach how to increase the maximum of 1000 operations/reagent additions per hour", it is important to recognize that, when the analyzer is operated per Fig. 5, the full number of cuvette ports 20 is underutilized (line 8, paragraph [0030]. In other words, the analyzer is initially installed with a "theoretical throughput of 3000 assays per hours"; however there are not sufficient reagent sources initially on-board to enable such a throughput. This means a laboratory can initially purchase a (lower cost) under-capacity analyzer and then add resources at a later time to increase capacity incrementally when the incremental cost of the throughput-limiting resource is more easily justified.

The Examiner recognized that "Table 2 is after the addition of a second reagent storage area . . . but the throughput for a single reagent is still 1000 since it does not matter which arms add the reagent." The explanation for this misunderstanding is given above, that the number of cuvette ports being utilized is also being increased.

The Examiner further concluded that "Throughput is only increased by the addition of the second reagent server when assays requiring two or three reagents are being performed." And "throughput is only increased by the addition of a third server when assays requiring three reagents are performed." The explanation for these mis-conclusions is also given above, that the number of cuvette ports being utilized is also being increased.

Applicant fully believes that one skilled in the art of designing analyzers, being informed that not all of the available cuvette ports are being used when only a single reagent server is available ([0030] above), would immediately recognize the necessity to supply addition cuvettes when a second reagent server was installed to add throughput. This necessity is again emphasized at the end of paragraph [0030], "the analyzer is originally configured so that other assay operational devices (cuvette supply) are also originally adapted to accommodate the addition of throughput limiting devices (e.g., reagent servers). This necessity is even further emphasized at the beginning of paragraph

[0031], "increase throughput level beyond that in which the capacity for conducting assays is limited only by the capacity of reagent servers." Since only the reagent servers limit throughput, Applicant respectfully disagrees with the Examiner's statement that the "application fails to teach how to increase the capacity to reach a throughput of more than 1000 assays/hour by adding reagent resources in an incremental manner."

In the Office Action dated January 17, 2006, Claims 1-5 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement. In making the rejection under 35 USC 112, the Examiner concluded that because "the disclosure does not teach if the added resources are limited to a single reagent, a set of reagents different from those initially present, a duplication of those originally present or some combination", then the claims were treated as covering the addition of capacity to perform new assays or to add multiple reagents simultaneously. As was explained in an earlier communication, this is not correct because important features of his invention include:

1) The menu of assays is not changed as servers are added; and,
2) Servers are not being added in order to introduce new reagents.

In support of this, the Examiner's attention is drawn to Fig. 5 and Table 1 where only one server 26 is installed and in which case, the throughputs for assays requiring 1-2-3 reagents are provided. Paragraph [0028] further explains that "Table 1 shows . . . analyzer 10 is equipped with the reagents required to perform assays having as many as 3 different reagents." For this reason, there is no justification for examining the claims as covering the addition of capacity to perform new assays or to add multiple reagents simultaneously. Claim 7 is presented in a manner to emphasize that the same group of assays is always being conducted and that new different assays are not being added.

For all of the reasons put forth above, it is believed to be very obvious to one skilled in the art of designing modern clinical analyzers that, if an analyzer is initially configured so that the full number of available cuvette ports is underutilized, then the available ports will be employed when throughput is desired to be increased. In view of the above reasonings, it is believed that the specification is fully enabling and respectfully requests the withdrawal of the rejection under 35 USC 112, first paragraph. If the Examiner disagrees, applicant requests the opportunity to provide affidavits by analyzer equipment and operating software engineers to this effect.

Claim Rejections –35 USC §102(b)

Claims 1-6 are rejected under 35 USC 102(b) as being anticipated by Jones (US 3,615,239). The Examiner cites Jones for teaching that the number of diagnostic tests to be performed by the analyzer may be increased by adding a further module. In the instance of Jones, however, each module is designed to implement a different assay and additional modules are added in order to add a new different assay to the analyzer's menu. As specified, Jones' analyzer is intended for use when a substantial number of different tests may be performed (Col. 1, lines 44-46) and that this may be accomplished by his invention since, "the programmer includes a plurality of modules, each being representative of the treatment required for a different diagnostic test." Each module has a rotatable disk with extending fingers that cause electrical contact to a device so that fluid is delivered or removed from a tube. Each disk programs a single separate test or operation. Lines 63-65 make this evident since, "the programmer includes a plurality of modules, each being representative of the treatment required for a different diagnostic test." Further, as the Examiner stated, "In the apparatus disclosed, five treatment stations are indicated although a greater or smaller number may be provided depending on the number and type of different diagnostic tests to be performed." To make this point clear, Claim 7 requires that the same group of assays always being conducted and that new different assays are not added.

Thus, Jones' modular programming disk has the effect of adding different assays to the analyzer's menu and does not affect throughput of the analyzer as does Applicant's claimed invention. Nowhere does Jones disclose the claimed step of initially configuring the analyzer with reagent resources that are throughput limiting in conducting a certain group of assays. Since Jones does not expressly or inherently disclose these features of applicant's now claimed invention, Jones cannot be said to anticipate the present invention and Applicant respectfully requests that the rejection over Jones be withdrawn.

Claim Rejections –35 USC §103(a)

Claims 1-5 are rejected under 35 USC 103(a) as unpatentable over Berglund (US 4,459,265) or Minekane (US 4,906,433) in view of Jones (US 3,615,239). Berglund discloses an analyzer wherein the number of reagent-supply stations and their location may be varied to suit different purposes. The Examiner recognizes that, "Berglund does

not teach modular configuration for the additional reagent-supply stations." Minekane's teachings are similar to Berglund's, in that Col. 7 lines 35-45 disclose reagent containers that may be positioned on different arcs, however, as the Examiner noted, "Minekane does not teach a modular configuration for the additional reagent storage locations."

As discussed above, Jones does not disclose the step of initially configuring the analyzer with reagent resources that are throughput limiting in conducting a certain group of assays. Thus the combination of Berglund and/or Minekane and Jones fails to make Applicant's invention unpatentable because no modification of the references teaches or even suggests initially configuring an analyzer with reagent resources that are throughput limiting for conducting a certain group of assays and at the same time configuring the analyzer with all other assay resources that are not throughput limiting for conducting the same assays. Applicant also claims incrementally adding reagent resources to the analyzer in order to increase throughput as the number of assays within the group of assays to be conducted increases and this feature cannot be replicated by any combination of the teachings of Berglund and/or Minekane and Jones. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness and it is requested that the rejection over Berglund or Minekane in view of Jones be withdrawn.

Applicant believes that this application contains patentable subject matter and that the foregoing amendments provide a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicant's representative at the number provided below.

Respectfully submitted,

Leland K. Jordan

Leland K. Jordan
Registration No. 36,560
Agent for Applicant

Dade Behring Inc.
1717 Deerfield Road
P. O. Box 778
Deerfield, IL 60015-778
(847) 267-5365